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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/088,047

Applicant(s)

MENDEZ, IVAR

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-7, 15-18, 21-33 and 35-37 is/are allowed.
- 6) ☒ Claim(s) 1 and 8-9, 11-14 is/are rejected.
- 7) ☒ Claim(s) 10, 19, 20 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

Art Unit: 3763

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/21/05 has been entered.

### ***Claim Objections***

Claims 1 and 2 are objected to because of the following informalities: the preamble of each recites "for use in combination with" which is imprecise for one cannot easily determine if the claim is directed to a device for use with a syringe or a device in combination with a syringe. It is suggested that the preamble be changed to one of the above. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

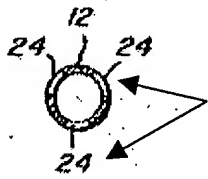
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,8-9,11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (USPN 4,710,180) in view of Shapiro et al (USPN 4,415,101). Johnson discloses a

Art Unit: 3763

syringe (see figure 1) with a barrel (6) and plunger (8) and cannula (4) having a single passageway (16) with an open upper end (18), a lower end (14) defining a blunt closed tip (22) and a pair of side port holes (24). The side port holes (24) are essentially diametrically opposed yet slightly offset from being completely diametrically opposed. See figure 4 below.



Pair of side port holes (24) that are diametrically opposed in that they are positioned on opposite sides of the diameter of the cannula but are slightly offset from being truly oppositely positioned.

**FIG. 4**

Regarding claims 8-9, the cannula (4) has a length that is sufficient to linearly penetrate and enter a host brain where the holes would be concurrently positionable at a predetermined target site. See figure 1. As shown in the drawing, the cannula has an outside diameter of **about** 0.8mm.

Regarding claims 11 and 14, as shown in figure 4 the side port holes (24) have the same diameter. The cannula is made from stainless steel. See 2:44.

Johnson meets the claim limitations as described above but fails to include a microinjector for incremental depression of the plunger to result in metered delivery of the contents of the syringe barrel through the cannula port holes.

Shapiro discloses an incremental liquid dispensing device that includes a syringe barrel (13), a plunger (15) and a microinjector (11). The microinjector is attached to the proximal end of the syringe (21) and the plunger (26). The microinjector is designed to incrementally drive the plunger. See Summary and 3:20-21.

Art Unit: 3763

At the time of the invention, it would have been obvious to incorporate the microinjector of Shapiro into the invention of Johnson to provide a controlled mechanism for injection. Both devices are analogous in the syringe/injection art; therefore, a combination is proper.

Additionally, one skilled in the art would recognize that a known problem exists in the art of manual injectors, such as the Johnson syringe. Manual injectors are subject to variations of injection pressure and volume. Furthermore, the application of Johnson may be greatly affected by fluctuations in injection pressure in that the changes of pressure may potentially alter or destroy the living cells being injected. Therefore, one skilled in the art would recognize the need for an automated incremental injector to provide a known injection volume and rate. One skilled in the art would have garnered the motivation for the incorporation in order to provide a solution to a known problem in the syringe art.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (USPN 4,710,180) in view of Shapiro et al (USPN 4,415,101). Johnson in view of Shapiro meet the claim limitations as described above but fail to disclose the side port holes having a diameter of 0.3mm and the microinjector being manufactured from acetal nylon and ionized aluminum.

At the time of the invention, it would have been an obvious design choice by one skilled in the art to make the side port holes the diameter as claimed. Applicant has not disclosed that the claimed diameter provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Johnson in view of Shapiro and applicant's invention to perform equally well with either the diameter as shown by

Art Unit: 3763

Johnson or the claimed diameter because either diameter would allow for the passage of a typical human cell assuming a cell diameter of about 10 microns. Therefore, it would have been obvious to modify Johnson in view of Shapiro with the claimed side port diameter because such a modification would have been a design consideration which fails to patentably distinguish over the prior art.

Further, the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

At the time of the invention, it would have been an obvious design choice by one skilled in the art to make the microinjector from the materials claimed. Applicant has not disclosed that the claimed materials provide an advantage, are used for a particular purpose or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Johnson in view of Shapiro and applicant's invention to perform equally well with either the materials of Johnson in view of Shapiro or the claimed materials because both materials would perform the same function of providing a microinjector with sufficient rigidity to depress the plunger to initiate an injection. Furthermore, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. Therefore, it would have been obvious to modify Johnson in view of Shapiro with the claimed materials because such a modification would have been a design consideration which fails to patentably distinguish over the prior art.

Art Unit: 3763

***Allowable Subject Matter***

Claims 10, 19-20 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 2-7, 15-18,21-33 and 35-37 are allowed.

***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.



Catherine S. Williams

April 1, 2005